

Food and Drug Administration, HHS

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§ 189.165 Nordihydroguaiaretic acid (NDGA).

(a) Nordihydroguaiaretic acid is the chemical 4,4'-(2,3-dimethyltetramethylene) dipyrocatechol, $C_{18}H_{22}O_4$. It occurs naturally in the resinous exudates of certain plants. The commercial product, which is synthesized, has been used as an antioxidant in foods.

(b) Food containing any added NDGA is deemed to be adulterated in violation of the act based upon an order published in the FEDERAL REGISTER of April 11, 1968 (33 FR 5619).

(c) The analytical method used for detecting NDGA in food is in section 20.008(b) of the "Official Methods of Analysis of the Association of Official Analytical Chemists International," 13th Ed. (1980), which is incorporated by reference. Copies may be obtained from the Association of Official Analytical Chemists International, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877-2504, or may be examined at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20408.

[42 FR 14659, Mar. 15, 1977, as amended at 49 FR 10114, Mar. 19, 1984; 54 FR 24900, June 12, 1989]

§ 189.175 P-4000.

(a) P-4000 is the chemical 5-nitro-2-n-propoxyaniline, $C_9H_{12}N_2O_3$. It is a synthetic chemical having a sweet taste about 4000 times that of sucrose, is not found in natural products at levels detectable by the official methodology, and has been proposed for use as an artificial sweetener.

(b) Food containing any added or detectable level of P-4000 is deemed to be adulterated in violation of the act based upon an order published in the FEDERAL REGISTER of January 19, 1950 (15 FR 321).

(c) The analytical methods used for detecting P-4000 in food are in sections 20.177-20.181 of the "Official Methods of Analysis of the Association of Official Analytical Chemists," 13th Ed. (1980), which is incorporated by reference. Copies may be obtained from the Association of Official Analytical Chemists International, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877-2504, or may be examined at the Office

of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20408.

[42 FR 14659, Mar. 15, 1977, as amended at 49 FR 10114, Mar. 19, 1984; 54 FR 24900, June 12, 1989]

§ 189.180 Safrole.

(a) Safrole is the chemical 4-allyl-1,2-methylenedioxy-benzene, $C_{10}H_{10}O_2$. It is a natural constituent of the sassafras plant. Oil of sassafras is about 80 percent safrole. Isosafrole and dihydrosafrole are derivatives of safrole, and have been used as flavoring compounds.

(b) Food containing any added safrole, oil of sassafras, isosafrole, or dihydrosafrole, as such, or food containing any safrole, oil of sassafras, isosafrole, or dihydrosafrole, e.g., sassafras bark, which is intended solely or primarily as a vehicle for imparting such substances to another food, e.g., sassafras tea, is deemed to be adulterated in violation of the act based upon an order published in the FEDERAL REGISTER of December 3, 1960 (25 FR 12412).

(c) The analytical method used for detecting safrole, isosafrole and dihydrosafrole is in the "Journal of the Association of Official Analytical Chemists," Volume 54 (Number 4), pages 900 to 902, July 1971, which is incorporated by reference. Copies are available from the Division of Food and Color Additives, Center for Food Safety and Applied Nutrition (HFS-200), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, or available for inspection at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20408.

[42 FR 14659, Mar. 15, 1977, as amended at 42 FR 56729, Oct. 28, 1977; 47 FR 11855, Mar. 19, 1982; 54 FR 24900, June 12, 1989]

§ 189.190 Thiourea.

(a) Thiourea is the chemical thiocarbamide, CH_4N_2S . It is a synthetic chemical, is not found in natural products at levels detectable by the official methodology, and has been proposed as an antimycotic for use in dipping citrus.

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(b) Food containing any added or detectable level of thiourea is deemed to be adulterated under the act.

(c) The analytical methods used for detecting thiourea are in sections 20.115–20.126 of the “Official Methods of Analysis of the Association of Official Analytical Chemists,” 13th Ed. (1980), which is incorporated by reference. Copies may be obtained from the Association of Official Analytical Chemists International, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877–2504, or may be examined at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20408.

[42 FR 14659, Mar. 15, 1977, as amended at 49 FR 10114, Mar. 19, 1984; 54 FR 24900, June 12, 1989]

§ 189.191 Chlorofluorocarbon propellants.

The use of chlorofluorocarbons in human food as propellants in self-preserved containers is prohibited as provided by § 2.125 of this chapter.

[43 FR 11317, Mar. 17, 1978]

Subpart C—Substances Prohibited From Indirect Addition to Human Food Through Food-Contact Surfaces

§ 189.220 Flectol H.

(a) Flectol H is the chemical 1,2-dihydro-2,2,4-trimethylquinoline, polymerized, $C_{12}H_{15}N$. It is a synthetic chemical not found in natural products, and has been used as a component of food packaging adhesives.

(b) Food containing any added or detectable level of this substance is deemed to be adulterated in violation of the act based upon an order published in the FEDERAL REGISTER of April 7, 1967 (32 FR 5675).

[42 FR 14659, Mar. 15, 1977, as amended at 58 FR 17099, Apr. 1, 1993]

§ 189.240 Lead solders.

(a) Lead solders are alloys of metals that include lead and are used in the construction of metal food cans.

(b) Food packaged in any container that makes use of lead in can solder is deemed to be adulterated in violation

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of the Federal Food, Drug, and Cosmetic Act, based upon an order published in the FEDERAL REGISTER of June 27, 1995.

[60 FR 33109, June 27, 1995]

§ 189.250 Mercaptoimidazoline and 2-mercaptoimidazoline.

(a) Mercaptoimidazoline and 2-mercaptoimidazoline both have the molecular formula $C_3H_6N_2S$. They are synthetic chemicals not found in natural products and have been used in the production of rubber articles that may come into contact with food.

(b) Food containing any added or detectable levels of these substances is deemed to be adulterated in violation of the act based upon an order published in the FEDERAL REGISTER of November 30, 1973 (38 FR 33072).

§ 189.280 4,4'-Methylenebis (2-chloroaniline).

(a) 4,4'-Methylenebis (2-chloroaniline) has the molecular formula, $C_{13}H_{12}Cl_2N_2$. It is a synthetic chemical not found in natural products and has been used as a polyurethane curing agent and as a component of food packaging adhesives and polyurethane resins.

(b) Food containing any added or detectable level of this substance is deemed to be adulterated in violation of the act based upon an order published in the FEDERAL REGISTER of December 2, 1969 (34 FR 19073).

§ 189.300 Hydrogenated 4,4'-isopropylidene-diphenolphosphite ester resins.

(a) Hydrogenated 4,4'-isopropylidene-diphenolphosphite ester resins are the condensation product of 1 mole of triphenyl phosphite and 1.5 moles of hydrogenated 4,4'-isopropylidene-diphenol such that the finished resins have a molecular weight in the range of 2,400 to 3,000. They are synthetic chemicals not found in natural products and have been used as antioxidants and as stabilizers in vinyl chloride polymer resins when such polymer resins are used in the manufacture of rigid vinyl chloride polymer bottles.

(b) Food containing any added or detectable levels of these substances is